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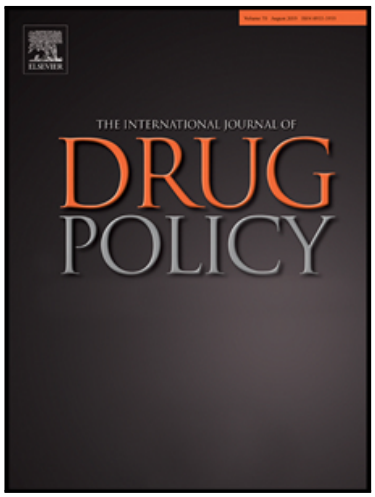

A rapid assessment of take-home naloxone provision during COVID-19 in Europe

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PII: S0955-3959(22)00202-X
DOI: https://doi.org/10.1016/j.drugpo.2022.103787
Reference: DRUPOL 103787

To appear in: *International Journal of Drug Policy*

Please cite this article as: Rebecca McDonald , Desiree Eide , Katri Abel-Ollo , Lee Barnsdale , Ben Carter , Thomas Clausen , Ed Day , Francina Fonseca , Elin Holmén , Kirsten Horsburgh , Mike Kelleher , Martin Kåberg , Martin Ladenhauf , Andrew McAuley , Nicola Metrebian , Joanne Neale , Stephen Parkin , Kevin Ratcliffe , Chris Rintoul , Josie Smith , Viktorija Stifanoviciute , Marta Torrens , Henrik Thiesen , John Strang , A rapid assessment of take-home naloxone provision during COVID-19 in Europe, *International Journal of Drug Policy* (2022), doi: https://doi.org/10.1016/j.drugpo.2022.103787

A rapid assessment of take-home naloxone provision during COVID-19 in Europe

Authors: Rebecca McDonald[1,2]*, Desiree Eide[1,2]*, Katri Abel-Ollo[3], Lee Barnsdale[4], Ben Carter[5,] Thomas Clausen[2], Ed Day[6], Francina Fonseca[7], Elin Holmén[8,9], Kirsten Horsburgh[10], Mike Kelleher[11], Martin Kåberg[8,12], Martin Ladenhauf[13], Andrew McAuley[4,14], Nicola Metrebian[1], Joanne Neale[1], Stephen Parkin[1], Kevin Ratcliffe[15], Chris Rintoul[16], Josie Smith[17], Viktorija Stifanoviciute[18], Marta Torrens[7], Henrik Thiesen[19], John Strang[1,11]

*Joint first authors

Author affiliations:

[1] National Addiction Centre, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK

[2] Norwegian Centre for Addiction Research, Institute of Clinical Medicine, University of Oslo, Norway

[3] Drug Abuse and Infectious Diseases Prevention Centre, National Institute for Health Development, Tallinn, Estonia

[4] Public Health Scotland, UK

[5]Department of Biostatistics and Health Informatics, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK

[6] Institute for Mental Health, School of Psychology, University of Birmingham, UK

[7] Addiction Research Group, Neuroscience Research Program, Hospital del Mar Medical Research Institute, Barcelona, Spain

[8] Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institute, Stockholm, Sweden

[9] Stockholm Needle Exchange, Stockholm Centre for Dependency Disorders, Stockholm, Sweden.

[10] Scottish Drugs Forum, Glasgow, UK

[11]South London and Maudsley NHS Foundation Trust, London, UK

[12] Department of Medicine, Division of Infectious Diseases, Karolinska Institute, Stockholm, Sweden

[13] Caritas Kontaktladen und Streetwork im Drogenbereich, Graz, Austria

[14] School of Health and Life Sciences, Glasgow Caledonian University, UK

[15] Change Grow Live, Birmingham, UK

[16] Cranstoun, Esher, UK

[17] Substance Misuse Programme, Public Health Wales, Cardiff, UK

[18] Drug, Tobacco and Alcohol Control Department, Lithuania

[19] Health Team for the Homeless, Center for Marginalized Adults and Families, Copenhagen City Social Services, Denmark

Short title: THN in Europe during COVID-19

Corresponding Author:
Dr Rebecca McDonald
Norwegian Centre for Addiction Research
Institute of Clinical Medicine
University of Oslo
Norway
Email: Rebecca.mcdonald@medisin.uio.no

Number of Tables: 3

Number of Figures: 0

Word count: 4591

Keywords: harm reduction, opioid, opiate, heroin, overdose, coronavirus

Abstract

Background

In March 2020, the World Health Organization declared COVID-19 a global pandemic. In the following weeks, most European countries implemented national lockdowns to mitigate viral spread. Services for people who use drugs had to quickly revise their operating procedures to rearrange service provision while adhering to lockdown requirements. Given the scarcity of literature published on overdose prevention during COVID-19 in Europe, we aimed to examine how these changes to service provision affected take-home naloxone (THN) programmes and naloxone availability across Europe.

Methods

Between November 2020 and January 2021, we conducted a rapid assessment with country experts from European countries that provide THN. We sent country experts a template to report monthly THN distribution data (January 1, 2019-October 31, 2020) and a structured 6-item survey for completion.

Results

Responses were received from 14 of the 15 European countries with THN provision of which 11 participated in the rapid assessment: Austria, Denmark, England, Estonia, Lithuania, Northern Ireland, Norway, Scotland, Spain (Catalonia only), Sweden, and Wales. All reported reduced organisational capacity during COVID-19, and some put into place a range of novel approaches to manage the restrictions on face-to-face service provision. In six countries, the introduction of programme innovation occurred alongside the publication of government guidelines recommending increased THN provision during COVID-19. Eight of the eleven participating countries managed to maintain 2019-level monthly THN distribution rates or even increase provision during the pandemic.

Conclusion

Through programme innovation supported by public guidelines, many European THN programmes managed to ensure stable or even increased THN provision during the pandemic, despite social distancing and stay-at-home orders affecting client mobility.

Background

On 11 March 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. In the two weeks that followed, most European countries (except for Sweden) ordered national lockdowns, which included social distancing and stay-at-home orders to slow down the viral spread (DW, 2020). Just like other healthcare facilities, services for people who use drugs had to quickly revise their operating procedures to rearrange service provision while adhering to social distancing requirements. There remains uncertainty on how the COVID-19 pandemic will ultimately affect people who use drugs, and the services they utilise (Costa Storti et al., 2021; Munro et al., 2021).

While the European Centre for Disease Prevention and Control does not formally recognise people who use opioids as a high-risk group for COVID-19 (ECDC, 2022), they face additional vulnerabilities compared to the general population (EMCDDA, 2020a; Marsden et al., 2020), including high prevalence rates of respiratory (COPD) and infectious (Hepatitis C, HIV) diseases, which may worsen clinical outcomes. Among people who use opioids who are infected with COVID-19, the risk of fatal opioid overdose may be elevated due to lung impairment

(EMCDDA, 2020a). People who use opioids may also face additional risks resulting from COVID-19-related disruptions to their opioid supply (illicit or prescribed) and to treatment services, including dispensing arrangements (EMCDDA, 2020a). For instance, dispensing guidelines in several countries were revised to allow for individual case-consideration of whether up to increased quantity of take-home supplies of buprenorphine and methadone could be given to ensure treatment access during the pandemic (Trayner, 2022). However, unsupervised consumption can increase the risk of overdose (Public Health England, 2021; Strang et al., 2010).

Take-home naloxone (THN) provision to people who use opioids is an effective public health strategy for preventing opioid overdose deaths (WHO, 2014), particularly when distribution rates reach high enough coverage (Strang et al., 2014; Walley et al., 2013). Reduced face-to-face contact in harm reduction and treatment services during COVID-19 may have required alternative distribution strategies. In a rapid global assessment conducted in August 2020, 53% of the reporting country experts cited partial or complete disruption to overdose prevention programmes (WHO, 2020). Moreover, naloxone can only be administered when overdoses are witnessed by others, and stay-at-home orders and bans on household mixing may have increased the rates of people using opioids on their own. COVID-19 restrictions may also have influenced the illicit drug market (UNODC, 2021) and COVID-19-related social isolation may have led to a greater proportion of people using opioids on their own, which is considered one of the key factors accelerating the trend of rising overdose deaths in North America (Friedman et al., 2021; Wakeman et al., 2020).

The relationships between THN provision, the COVID-19 pandemic, and non-fatal or fatal overdose rates remain unclear, as official data on drug-related deaths for 2020 are yet to be published for most of Europe. England and Catalonia (Spain) recently reported a record number of drug-related deaths registered in 2020, although some of these deaths occurred in 2019, i.e., preceding the pandemic (Catalan Public Health Agency, 2021; Office for National Statistics, 2021). Similarly, in Scotland, a spike in drug-related deaths occurred during lockdown months (National Records of Scotland, 2021). In the United States, where the COVID-19 pandemic has overlapped with the ongoing opioid endemic, record opioid mortality has been reported for 2020 (Centers for Disease Control, 2020b, 2020a). In Canada, people who use drugs reported

disruptions in drug supply during the pandemic, which made them more vulnerable to using potentially adulterated substances and experiencing overdoses (Ali et al., 2021).

For several reasons, estimating the impact of COVID-19 on drug-related deaths in Europe is complicated. Firstly, a rise in drug-induced deaths in Europe (with 76% from opioids) has been observed since 2018 (EMCDDA, 2021a), i.e., predating the pandemic. Opioid mortality is multicausal, with other factors such as changes in illicit opioid supply and access to opioid substitution treatment during COVID-19 needing to be considered. In this regard, COVID-19 is an added event which has produced further changes in the context of a pre-existing, already complex problem. Secondly, data collection itself may be influenced in various ways. The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) has itself pointed out that, due to pressures from the COVID-19 emergency response (including staff transfer to other units), some of its national focal points may face significant delays in the reporting of drug-related monitoring activities (EMCDDA, 2020b). Thirdly, there are general changes to the European data infrastructure because of Brexit (i.e., the withdrawal of the United Kingdom from the European Union on 31 January 2020), which coincided with COVID-19. The 2021 European Drug Report (EMCDDA, 2021a) is the first not to report on United Kingdom (UK) data, and the EMCDDA has noted the loss of relevant subject expertise (Watson, 2021). Lastly, inconsistent data collection methods and analyses vary between countries, creating uncertainty about case definitions and making between-country comparisons difficult (Millar & McAuley, 2017).

Given the scarcity of literature published on overdose prevention during COVID-19 in Europe, it is unclear if changes to THN provision are representative of changes to programmes across European countries. Therefore, the aim of this study was to assess the impact of COVID-19 on THN provision across Europe.

Methods

Design

Ecological rapid assessment consisting of consultations with country experts for THN programmes in Europe. Rapid assessments are widely used for a variety of public health research, including the area of illicit drug use. As Rhodes et al. (Rhodes et al., 1999) have

argued, *"rapid assessment methods are well suited to the undertaking of cost-effective and pragmatic research […], particularly when inadequate data exist"* (p. 66).

Setting and eligibility

According to the EMCDDA (EMCDDA, 2020c), THN programmes existed in 15 European countries at the time of data collection: Austria, Denmark, England (UK), Estonia, France, Germany, Ireland, Italy, Lithuania, Northern Ireland (UK), Norway, Scotland (UK), Spain, Sweden, and Wales (UK).

These programmes differed in the scale and length of implementation. First THN distribution in Europe occurred as early as 1991 in Italy (on an experimental basis), where around 15,000 naloxone vials are annually distributed through drugs agencies today. Early adoption followed at individual sites in the UK and Germany in the late 1990s/early 2000s, whereas most European THN programs were introduced or formalised in the 2010s (see supplementary material). According to EMCDDA (EMCDDA, 2020c), the countries with highest total volumes in THN distribution are Scotland (>46,000 kits), France (>25,000 kits), and Norway (>13,000 kits). No THN programs were operational in the following countries at the time of data collection: Belgium, Bulgaria, Croatia, Cyprus, Czechia, Finland, Greece, Hungary, Latvia, Luxemburg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, and Turkey (EMCDDA, 2020c). Countries were eligible for inclusion in the study if they 1) had at least some THN provision at local, regional, or national level and 2) responded to the data query.

Study instruments

To capture changes to THN provision, two study instruments were developed by the first two authors based on programme indicators used for THN distribution in the EMCDDA country profiles (EMCDDA, 2020c). An Excel template was generated requesting monthly THN distribution rates (i.e., the number of THN kits by month) for all sites for January 1, 2019-December 31, 2019, and January 1, 2020 – October 31, 2020 (see Table 1, Q1). The study instrument requested information for the number of kits distributed and the number of sites ("Please document your monthly THN distribution rates in 2019 and 2020") but did not ask for the number of units (ampoules, pre-filled syringes, nasal sprays) of naloxone provided in each kit.

In addition, a 6-item questionnaire (see Table 1, Q2-Q7) was developed that included the following topics: the general characteristics of the THN programme (Q2, Q3, Q4), any changes in THN provision due to COVID-19 (Q5), the introduction of COVID-19-specific guidelines (where applicable, Q6), and any reported changes in opioid use and overdose since onset of the pandemic (Q7). The questionnaire allowed the experts to enter a mix of free-text and tick-box responses (see Table 1). We sent the identified country experts (see below) the questionnaire and Excel template. Country experts returned the completed the questionnaire and Excel spreadsheet with their information via email by January 31, 2021.

Identification of country experts

Experts from all 15 European countries with THN provision were invited to participate in this rapid assessment by the first authors. Where expert contacts were not already known to the authors, one contact per country was obtained via the EMCDDA. In November 2020, an email was sent out to contacts from all 15 countries requesting relevant information. A reminder email was sent after seven days. Where no response was obtained from a country expert, an alternative person working in addictions research or overdose prevention in this country was contacted. This person was selected based on referral from the original contact, or their publicly accessible data (e.g., publications) in overdose prevention in their country. Countries in which experts did not respond or were unavailable to provide data were not included in the report.

Country experts had various roles within their respective countries. Some were in positions directly distributing THN, while others had roles more centrally in public health positions or as researchers. At the point of our data collection, the experts reported the best available data from local THN sites or national databases. Data were not necessarily exhaustive or representative of an entire country. As such, the data provided cannot be considered as a complete picture for all countries. All participating country experts are included as co-authors.

[INSERT TABLE 1 HERE]

Statement of Ethics

The research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. Data were collected to assess current THN services and included program-level data with no personally identifiable human subject data collected. This therefore can be considered a 'service evaluation' and ethics approval was not required (Framework for Health and Social Care Research, 2017). No funding was received for this assessment.

Analysis

Monthly THN distribution rates were totalled for Q1. This methodological approach has previously been reported by Courser and Raffle (Courser & Raffle, 2021). As this was an ecological study presenting descriptive aggregate level data, we did not perform statistical analysis of the distribution data, which would be beyond the scope of this paper.

Quantitative data relating to Q1-Q3 and Q6-Q7 were entered into an Excel spreadsheet. Responses for Q6-Q7 were tabulated (yes/no), and any additional information provided was summarised. Responses for Q4 were summarised based on distribution points, target populations, and funding for each country. The open-text responses relating to Q5 were listed verbatim in a Word document and grouped into three categories following the basic principles of Iterative Categorization (Neale, 2016): (1) less distribution, (2) more distribution, and (3) change in distribution approach. Responses relating to each of the three headings were further organised into the subheadings as reported below.

Results

Country participation

Responses were received from fourteen of the fifteen invited country experts (response rate 93%). No response was obtained from France. Experts from Germany, Ireland, and Italy stated that they were unable to participate in the rapid assessment due to capacity limitations amidst the COVID-19 emergency response. The contact person from Germany reported reduced capacity to distribute THN, and the contact persons from Ireland and Italy reported limited capacity to collect or share data. Therefore, these three countries were not included in this report.

Among the 11 participating experts, there were varying degrees of access to data (national, regional, local). Seven experts had access to and reported national-level data: Denmark, Estonia, Lithuania, Northern Ireland, Norway, Scotland, and Wales. The Regional Public Health Authority in Catalonia (Spain) reported regional level data and did not provide data for other regions in Spain. Austria, England, and Sweden provided local site-level data.

Consistent with EMCDDA reporting, the term "countries" is used throughout this report to refer to all participating areas regardless of level of data or scale of implementation (national, regional, local).

Take-home naloxone distribution rates

Average monthly THN distribution rates by country were generated to observe any changes between 2019 (pre-COVID-19) and 2020 (see Table 2). Except for declines in Austria, Estonia, and Catalonia (Spain), all countries maintained or increased THN distribution between 2019 and 2020. The largest percentage increase in distribution was reported by Northern Ireland (62.8% compared to past-year, equalling 57 kits), with Scotland reporting the highest total volume increase (477 kits more than past-year, equivalent to 44.2% increase).

In addition, THN distribution rates per 100,000 population (averaged for 2019 and 2020) were calculated (see Table 2), ranging from 0.02 (Austria) to 24.07 (Scotland) kits per 100,000 population.

[INSERT TABLE 2 ABOUT HERE]

Take-home naloxone programme characteristics

Overall, prior to the COVID-19 pandemic there was similarity in country THN programme characteristics. Details for THN programme characteristics pre-COVID-19 (incl. type of naloxone provided) and funding source can be found in the Supplementary Material. While funding streams vary across countries, eight country experts reported THN funding to be

primarily from the central government or public health authorities. Three country experts reported public funding to be from local level (Austria, Denmark, and England), with Denmark reporting private charity support in addition to public funds (see supplementary material). No countries reported shortages of naloxone. Among all 11 countries, the types of distribution sites were comparable. All country experts reported that THN sites included low-threshold facilities, addiction treatment facilities, shelters, or street outreach. All country experts reported that the target group was people who use opioids, with additional targeting in some countries towards friends and relatives of people who use opioids and professionals working with people who use opioids. Police being equipped with naloxone was reported for England (Birmingham only), Norway, and Scotland.

Key changes during the COVID-19 pandemic

Country experts were asked about key changes to *how* THN was distributed during the COVID-19 pandemic. Various changes were reported, and these changes were multidirectional in their potential impact on THN distribution volume. The factors reported were categorised as contributing towards less distribution, more distribution, and changes in the distribution approach. Factors relating to less distribution were organised into the following sub-categories: a) service closure, b) reduced service delivery, c) no or reduced training, and d) funding issues. Factors relating to more distribution are categorised into a) street outreach and b) high-volume distribution. Factors relating to changes in distribution were organised as a) novel approaches and b) hygiene measures.

Key changes are described in the following section, and Table 3 illustrates absolute numerical changes in THN provision (increased or decreased) in the left column and the key changes as factors underpinning increases and decreases in THN provision in the right columns.

<u>Factors towards less distribution</u>

Service closure

Service closures were reported by Austria, Lithuania, Northern Ireland, and Catalonia (Spain). In Lithuania, inpatient treatment services were suspended. One fixed-site needle exchange in Northern Ireland was closed (however this was due to local community pressure rather than

COVID-19 and THN was later supplied via a separate channel). In Austria, all THN education halted during lockdown (March-June 2020), and Catalonia (Spain) saw the closing of three harm reduction centres.

Reduced service delivery

For countries where services were not entirely closed, there were still reports of reduced service delivery. Seven country experts reported reduced service delivery in the forms of limited opening hours (Denmark, Estonia, Lithuania, Catalonia (Spain), and Wales), and staff reductions (England, Norway, and Wales). Staff reductions related to COVID-19 infections, quarantine or isolation rules, or general reductions to having face to face contact and staff on site. In addition, the expert from England reported fewer new presentations of patients coming into service, and in Northern Ireland several areas saw the stopping of inducting new patients on opioid maintenance treatment (OMT) (e.g., buprenorphine, methadone).

No or reduced training

Experts from Austria, Denmark, and Sweden reported either reduced or complete cessation in THN training and distribution. In Denmark, there were limits on the number of people that were permitted to gather, so impacting training. The experts from Sweden and Denmark reported COVID-19 adaptations that affected elements of training, such as difficulty practicing the physical elements such as difficulty practising the recovery position and CPR training.

Funding difficulties

One country (Denmark) reported difficulties relating to funding THN during the COVID-19 pandemic. According to the Danish country expert, local funding did not end up in the treatment systems, and the co-ordination of local community funding was delayed during the first lockdown in March 2020, which impacted THN distribution.

<u>Factors towards more distribution</u>

Two factors were reported that had the potential to increase THN distribution volume, a) street outreach and b) high-volume distribution. These efforts were reported in six countries (England, Lithuania, Northern Ireland, Catalonia (Spain), Sweden, and Wales). Northern Ireland, Catalonia

(Spain), and Wales all reported increased street outreach. Meanwhile, England reported a "surge in distribution" (a sudden rapid increase in THN distribution), the Lithuanian expert reported increased demand for THN, and the Swedish expert reported prioritised access to THN at needle and syringe programs. Similarly, Estonia and Northern Ireland reported distributing multiple THN kits per encounter. Wales reported increased efforts across all 60 THN sites to issue naloxone to those at risk, and Northern Ireland reported an emphasis of offering THN at every contact with the target group. These factors were *efforts* reported by countries to potentially improve THN distribution volume, and actual reports of increased rates of THN distribution are presented in Table 2.

Changes in distribution approaches

Further, eight countries (England, Estonia, Denmark, Northern Ireland, Scotland, Catalonia (Spain), Sweden, and Wales) reported changes in existing THN distribution to adapt to changes imposed by COVID-19. Factors relating to changes in distribution were organised into two sub-categories: a) novel approaches and b) hygiene measures.

Novel approaches

Scotland enacted several changes to traditional THN distribution during the COVID-19 pandemic. The ability to supply THN from non-drug treatment services, and as a result, postal delivery of naloxone was implemented following a decision of the Lord Advocate on 27 April 2020. A pilot using ambulance services as a THN distribution point began in February 2020, with its implementation coinciding with the COVID-19 period. Other countries reported novel approaches to THN distribution by coupling it with OMT, such as staff driving to pharmacies to deliver THN alongside OMT (England) and THN provided to all of those enrolled in treatment with OMT (Scotland). Prior to the pandemic, Norway had initiated the digitalisation of various elements of their THN programme (e-learning trainer course, online data collection, training video). Therefore, these digital resources were already in place and could be utilised to expand the programme during COVID-19 as a compensatory measure for handling restrictions. The expert from Northern Ireland also reported the introduction of postal naloxone and online training.

Hygiene measures

There were also reports of changes in how THN distribution sites operated, such as improving hand hygiene and cleaning of equipment, as reported by the experts from Denmark and Wales. The expert from Wales reported specific funding that was allocated to enable an increase in personal protective equipment and cleaning costs.

[INSERT TABLE 3 ABOUT HERE]

Guidelines changes

Specific guideline changes in THN provision since the start of the pandemic were reported in six countries. The Swedish Board of Health and Welfare recommended COVID-19-related adjustments to provision with prioritised distribution of THN (Socialstyrelsen, 2020). Sweden also prioritised increased access to the THN programme at Stockholm's needle and syringe services. Welsh COVID-19 guidelines emphasised the need to proactively ensure that all of those at risk of overdose were provided with THN prior to lockdown. In addition, Welsh guidance on THN provision and use of PPE in overdose situations was published in March 2020. In Scotland, guidelines allowed for the distribution of naloxone to occur from non-drug treatment services, as well as the introduction of home delivery of OMT medication alongside delivery of THN (Scotland's Prosecution Service, 2020). Public Health England released guidelines for commissioners and service providers in April 2020, stating that "measures to reduce drug […] related harm, such as needle and syringe programmes (NSP) [and] take-home naloxone […] should all be increased where possible" (Public Health England, 2021). Estonian and Northern Ireland THN guidelines have been revised to allow for more kits to be distributed per person per visit.

Changes in opioid use and overdose

Most countries reported that official data on fatal and non-fatal overdoses for 2020 were unavailable at the time of survey. For many countries, reporting any observed changes in opioid use or fatal and non-fatal overdoses was therefore provisional. However, Denmark reported that there was anecdotal evidence from drug consumption rooms that locally people had changed their patterns of use due to drug delivery shortages, in some cases leading to increased polydrug

use. The experts from Sweden and Norway also reported similar suspected heroin and other drug shortages (Lindqvist et al., 2021).

Discussion

Our findings indicate that nearly all European countries in this rapid assessment experienced restrictions on face-to-face service provision of THN during COVID-19. To compensate for limited client encounters, some countries introduced novel approaches to THN provision, such as concerted efforts to issue naloxone to all drug treatment clients on an opt-out basis, the introduction of postal delivery of THN kits, the scaling up of THN provision via street outreach as well as the provision of online overdose prevention training. In addition, THN programs in half a dozen European countries increased the number of THN kits distributed per client encounter. In six of the participating countries (England, Estonia, Northern Ireland, Scotland, Sweden, Wales), the introduction of such programme innovations occurred alongside the publication of government guidelines recommending increased THN provision during COVID-19.

Eight out of the eleven participating countries managed to maintain 2019-level monthly THN distribution rates or even increase provision during the pandemic. Decreases in THN distribution rates were only reported by Austria (due to a halt of the overdose prevention programme from March-June 2020), Estonia (where service opening hours were reduced) and Catalonia (Spain).

Novel approaches and increased distribution were seen in countries or sites with long-standing THN programs: England (local provision since 2001), Norway (established 2014), and Scotland (established 2011). Low-volume distribution during COVID-19, such as the provision of less than 30 kits/month (or less than 1 kit/day) in Austria and Denmark, were potentially linked to funding issues and service closures as well as reduced capacity for training. However, it should be noted that country experts from Norway pointed out that the increase in naloxone distribution may have been affected by the expansion of THN programmes and therefore cannot be attributed solely to COVID-19 novel approaches.

To our knowledge, our study is the first to conduct a rapid assessment of THN provision in Europe during the pandemic. To date, literature on this topic has primarily existed from North

America. As early as July 2020, U.S. authors alerted to the dangers of the overlapping opioid and COVID-19 epidemics, pointing to an attentional shift away from overdose response to containing the spread of COVID-19 (Collins et al., 2020). The authors noted that "removing regulatory barriers that limit access to THN is an important step to addressing overdose risk amid this pandemic" (p.2) (Collins et al., 2020). A research report by Courser and Raffle (Courser & Raffle, 2021) evaluated how four rural communities in the state of Ohio in the United States adjusted local overdose prevention programs during the pandemic, identifying the introduction of drive-throughs as THN distribution points as a key strategy for not just maintaining but significantly improving naloxone access during COVID-19.

The findings from the US are important but may be unlikely to be generalisable to the settings of many European THN programs, which are operating out of urban treatment and harm reduction sites, serving a population with limited or no access to cars (among whom drive-throughs would likely have minimum uptake). However, we were able to replicate the methodology, using the comparison of monthly THN distribution rates pre/during COVID-19 as the key outcome. Further, our systematic outreach to all European countries with existing THN provision at the time of data collection resulted in a good response rate (93%; 14/15 countries) for this rapid assessment of multi-country data.

Implications for policy and clinical practice

Our data underscore the importance of contingency planning for THN provision during the COVID-19 pandemic. As different viral strains emerge, the pandemic situation remains difficult to predict. However, our rapid assessment highlights that contingency planning for reduced face-to-face encounters can involve the following strategies: maximisation of the "output" of limited face-to-face encounters by providing multiple kits at a time, "contactless" THN kit provision (e.g., mail delivery) as well as the co-prescribing of THN to all clients in OMT on an opt-out basis.

Due to the observational nature of our data, caution must be exercised before drawing any causal conclusions from the reported level of THN provision on its effect on health outcomes in people who use opioids. Firstly, health outcomes in people who use opioids are multifactorial, and, as preliminary findings suggest, COVID-19 has impacted injecting drug use patterns as well as

access to various harm reduction services (including needle and syringe programmes and HIV/HCV testing) (Croxford et al., 2021, Trayner et al., 2022). Secondly, our study period is limited to the first wave of pandemic (i.e., preceding the introduction of COVID-19 vaccines), when a variety of temporary support measures were put in place that were later revoked. For instance, in England, supportive accommodation was available from March 2020 through the "Everyone In" initiative which offered free housing in local hotels to people experiencing rough sleeping (Parkin et al., 2021), and a moratorium on evictions for tenants was put in place (Public Health England, 2022). Any protective effects of such social support measures that were available to people who use opioids during the first wave of pandemic and later revoked will also need to be taken into consideration.

Lastly, there is uncertainty as to how any of these changes to normal service delivery that were implemented during the pandemic will impact health outcomes, as these studies have not been done yet. In terms of overdose mortality, Scotland and England reported a continuing increase in the number of drug-related deaths registered in 2020 (National Records of Scotland, 2021; Office for National Statistics, 2021). Norway reported the highest rate of fatal overdoses in twenty years for 2020, with an uptick in fatal overdose rates between June-August 2020, which coincided with the temporary closure of supervised injecting facilities (Gjersing, 2021). However, this seasonal increase has been seen in previous summers with non-fatal overdoses (Madah-Amiri et al., 2017). Due to the correlational nature of the data, no conclusions can be drawn, and more studies will need to be conducted to study how changes during the pandemic impacted overdose mortality.

Methodological considerations

Limitations include the observational nature of the study, and that we were unable to obtain data from France, Germany, Italy, and Ireland. This represents a potentially significant omission: Ireland has some of the highest per capita opioid mortality rates in Europe (EMCDDA, 2021b), whereas the former three countries are the most populous in the European Union, jointly accounting for nearly half (47%) of European Union citizens (Eurostat, n.d.). The lack of response from France is unfortunate, as their scale of implementation is among the highest in Europe, with a total volume of around 25,000 THN kits distributed according to EMCDDA figures (EMCDDA, 2020c). Italy has been one of the hardest hit European countries in terms of

per capita COVID-19 mortality (Statista, 2022). Our inquiry to the Italian Ministry of Health for information on THN provision was met with the response that the relevant staff were preoccupied with COVID-19 emergency response, and our contact persons from Germany and Ireland also mentioned capacity limitations, which only speaks to the challenges of conducting research *about* a pandemic *during* a pandemic.

A further limitation concerns the fact that some of the data were provided at country level (e.g., Scotland, Norway) and others at individual site level (e.g., Austria, England). This may impact data quality, where the expertise and rigorous scrutiny that national datasets typically receive may not be applied at local level. Further, there is a possibility for response bias in that countries

Another consequence is that the absolute rates of THN provision are not comparable across reporting countries. For instance, there is no central data monitoring for THN provision in England. Data from England were obtained from individual THN distribution sites in two cities, whereas the data for Scotland and Wales represented their national naloxone programmes in their entirety. To provide an overview of monthly THN distribution volume relative to population size, per capita rates were included in Table 2. However, it should be noted that this estimate is based on the total population and therefore different from the "reach of THN" (as reported by the Scottish national naloxone programme), which is defined as the annual THN distribution kit volume per 1,000 people with problematic drug use (Public Health Scotland, 2022). A more appropriate indicator for future research could thus be to determine THN coverage as a function of THN kits distributed adjusted by the population size of people who use opioids in the reporting area.

Lastly, the free-text option in the questionnaire meant that country experts may not have entered the same level of detail. However, the experts had the opportunity to add any potentially omitted information at various stages of the manuscript revision.

Questions for future research

It is worth noting that the latest EMCDDA infographic "Availability of take-home naloxone programmes in Europe", which was published in December 2021, i.e., after data collection for the present study, indicates the recent introduction of pilot THN provision in Belgium, Czechia, Cyprus, Slovenia, and Portugal (EMCDDA, 2021c). Considering the evolving pandemic, we believe that a repetition of this rapid assessment at regular (e.g., annual) intervals would be a

worthwhile exercise for monitoring THN provision and trends in opioid mortality across Europe over time, and this research should then also include Belgium, Czechia, Cyprus, Slovenia, and Portugal or any further countries introducing THN.

Conclusion

Through programme innovation supported by public guidelines, many European THN programs managed to ensure stable or even increased provision of THN kits during the pandemic, despite social distancing guidelines and stay-at-home orders affecting client mobility. Future research should examine any relationship between COVID-19-triggered changes in naloxone provision, wider harm reduction measures, and national data on overdose deaths, as well as synthesise the lessons learnt by THN programs internationally in terms of effective strategies for emergency response. In addition, a rapid assessment should be repeated in future to map national opioid-related mortality data during the pandemic when available.

Tables

Table 1 Overview of study instruments

Question	Instrument	Item	Instructions
Q1	Excel spreadsheet	Monthly THN distribution[1]	Pre-COVID-19: January 1-December 31, 2019 During COVID-19: January 1-October 31, 2020
Q2	Questionnaire	Country	
Q3	Questionnaire	Number of sites	
Q4	Questionnaire	Please briefly describe the THN programme in general, i.e., what THN distribution looks like in non-COVID-19 times.	What are the main distribution points (e.g., harm reduction services, treatment sites) and target populations? How is THN generally funded (private sources, government)?
Q5	Questionnaire	Please describe any key changes to THN distribution since March 2020, i.e., since start of the COVID-19 pandemic in Europe.	These can include organisational changes, such as facility opening hours or closings, staffing, methods for naloxone distribution, engaging target populations, funding changes, etc.
Q6	Questionnaire	Have guidelines for THN provision or administration changed since start of the COVID-19 pandemic (March 2020)?	Yes ☐ No ☐ If yes, describe:
Q7	Questionnaire	Are you already seeing any impact (positive or negative) of COVID-19 on the rate of non-fatal or fatal overdoses?	Yes ☐ No ☐ If yes, describe:

Table 2 Take-home naloxone distribution average and changes, reported as numbers of kits

Country	Data level	Average monthly distribution		Change (Δ 2020-2019)	Population[6]	Average[5] monthly distribution rate per 100,000 population
		2019 Period: 01.01.2019 – 31.12.2019	**2020** Period: 01.01.2020-31.10.2020			
Austria	Site[1]	3 (SD: 2.0) Range: 0-7	1 (SD: 1.8) Range: 0-5	-66.6%	8,916,860	0.02
Catalonia (Spain)[2]	Region	71 (SD: n/a) Range: n/a	43 (SD: n/a) Range: n/a	-39.4%	47,363,420	0.12
Denmark	Country	0 (SD: 0) Range: 0-0	18 (SD: 18.4) Range: 0-55	n/a	5,831,400	0.15
England	Site(s)[3]	144 (SD: 16.5) Range: 7-56	164 (SD: 16.3) Range: 3-58	+13.8%	56,550,000	2.72
Estonia	Country	62 (SD: 11.1) Range: 45-83	51 (SD: 16.3) Range: 31-83	-17.7%	1,329,480	4.25
Lithuania	Country	100 (SD: 60.0) Range: 29-194	129 (SD: 71.0) Range: 33-271	+29.0%	2,794,890	4.10
Northern Ireland	Country	91 (SD: 35.4) Range: 44-163	148 (SD: 10.1) Range:131-168	+62.6%	1,896,000	6.30
Norway	Country	311 (SD: 121.4) Range: 208-533	348 (SD: 42.8) 292-410	+11.9%	5,379,480	6.13
Scotland	Country	1,077 (SD: 132.9) Range: 857-1,317	1,554 (SD: 1,004.8) Range: 1,040-3,993	+44.2%	5,466,000	24.07
Sweden	Site(s)[4]	99 (SD: 17.9) Range: 64-126	116 (SD: 12.9) Range: 99-138	+17.2%	10,353,440	1.04
Wales	Country	389 (SD: 54.6) Range: 309-476	389 (SD: 70.0) Range:272-532	0%	3,170,000	12.27

[1] From one site in Graz (Steiermark)
[2] Catalonia (Spain) distributed 2 ampoules per THN kit. Data is reported as number of visits, not number of doses distributed.
[3] From four sites in England (London, Birmingham, Solihull, Wolverhampton)
[4] Stockholm does not always give two nasal sprays per visit (some just given one spray). Data is reported on the number of visits, not number of sprays distributed.
[5] Pooled 2019-20 average THN monthly distribution rates
[6] Sources: The World Bank (Population, total - Sweden, Lithuania | Data (worldbank.org); Office for National Statistics (https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/annualmidyearpopulationestimates/mid2020)

Table 3 Take home naloxone distribution volume changes and change factors

	Q1: 2019 vs. 2020 THN kits			**Q5: Change factors towards:**							
	Decrease	**Increase**	**No change**	**Less distribution**				**More distribution**		**Change in approach**	
				Service closure	Reduced service delivery	No or reduced training	Funding issues	Street outreach	High-volume distribution	Novel approaches	Hygiene measures
Country											
Austria	X			X		X					
Catalonia (Spain)	X			X	X			X			
Denmark		X			X	X	X				X
England		X			X				X	X	
Estonia	X				X				X		
Lithuania		X		X	X				X		
Northern Ireland		X		X				X	X	X	
Norway		X			X					X	
Scotland		X								X	
Sweden		X				X			X		
Wales			X		X			X	X		X

Acknowledgements

The authors would like to thank Dagmar Hedrich, Jane Mounteney, and Katrin Oien at EMCDDA for their support in identifying country experts for THN programmes in Europe. The authors would also like to thank Gabi Becker and Tim Bingham for their interest in the project.

Data Availability Statement

Data available upon reasonable request.

Declarations and Ethics

Competing interests: Declaration of Competing Interest in the last 3 years (authors listed in alphabetical order):

Katri Abel-Ollo: KAO has no competing interests.

Lee Barnsdale: LB has no competing interests.

Ben Carter: BC has received, through his university research funding from Mundipharma Research Ltd.

Thomas Clausen: TC has no competing interests.

Ed Day: ED has no competing interests.

Desiree Eide: DE has no competing interests.

Francina Fonseca: FF has no competing interests.

Elin Holmén: EH has no competing interests.

Kirsten Horsburgh: KH has no competing interests.

Mike Kelleher: MK, in the past 3 years, has taken part in research funded by Indivior, Camurus and Mundipharma. He has received honoraria from Indivior, Gilead, and Abbvie.

Martin Kåberg: MKå has received honoraria for lectures/consultancy from Abbvie, Gilead, MSD, Mundipharma, DnE Pharma, and Nordic Drugs and has received research grants from Gilead and Nordic Drugs.

Martin Ladenhauf: ML has no competing interests.

Andrew McAuley: AMcA has no competing interests.

Rebecca McDonald: RMcD indirectly received, through her former employer King's College London, funding from Mundipharma Research Ltd that supported her position of employment (2019-21). RM was supported by the National Institute for Health Research (NIHR) Biomedical Research Centre for Mental Health at South London and Maudsley NHS Foundation Trust and King's College London.

Nicola Metrebian: NM has received, through her university, King's College London, research funding from Mundipharma Research Ltd (a pharmaceutical company that produces a naloxone nasal spray). She has also received, through her university, consultancy payment from an agency for Mayne Pharma International, on another area of research not relevant to the article under consideration.

Joanne Neale: JN has received, through her university, research funding from Mundipharma Research Ltd and Camurus AB for unrelated research and an honorarium from Indivior for an unrelated conference presentation. JN was supported by the National Institute for Health Research (NIHR) Biomedical Research Centre for Mental Health at South London and Maudsley NHS Foundation Trust and King's College London.

Stephen Parkin: SP has received funding, as part of his employment within King's College London, funding from Mundipharma Research Ltd, and Camurus AB pharmaceutical company and The Pilgrim Trust. SP was supported by the National Institute for Health Research (NIHR) Biomedical Research Centre for Mental Health at South London and Maudsley NHS Foundation Trust and King's College London.

Kevin Ratcliffe: KR has no competing interests.

Chris Rintoul: CR has no competing interests.

Josie Smith: JS has no competing interests.

Viktorija Stifanoviciute: VS has no competing interests.

John Strang: JS has been a longstanding advocate for, and research enquirer into, take-home naloxone. Through his university, JS has worked/is working with pharma and tech industries to identify new or improved interventions (including overdose crisis management) and his employer (King's College London) has received grants, travel costs and/or consultancy

payments; this includes discussion and investigation of new naloxone formulations with, past 3 years, Mundipharma, Accord, dne pharma (all of whom have naloxone products). JS is currently leading a cohort study of individuals to whom a supply of take-home naloxone has been provided and who are being followed up prospectively over time, supported by an investigator-initiated grant from Mundipharma. His employer (King's College London) also earlier registered intellectual property on a buccal naloxone formulation, naming JS and colleagues, and he was previously named in a patent registration by a pharmaceutical company regarding concentrated nasal naloxone spray. JS does not receive any personal payment from these arrangements. JS was supported by the National Institute for Health Research (NIHR) Biomedical Research Centre for Mental Health at South London and Maudsley NHS Foundation Trust and King's College London. For a fuller account, see JS's web-page at http://www.kcl.ac.uk/ioppn/depts/addictions/people/hod.aspx

Marta Torrens: MT has been a consultant/advisor and/or speaker for Gilead Sciences, Merck Sharp & Dohme Corp, Indivior, Mundipharma Pharmaceutics, Servier Adamed, Lundbeck, Camurus, and Rovi**.**

Henrik Thiesen: HT has no competing interests.

Ethical approval

Have you obtained ethical approval for the conduct of your study? Please answer yes or no.

No.

Funding sources for the work

None.

Author Contributions

RM and DE designed the study, drafted, and co-wrote the manuscript. The remaining co-authors provided data and valuable feedback for their respective countries. All co-authors helped to shape the analysis and offered critical feedback. All authors approved its final version.

SUPPLEMENTARY MATERIAL

General THN programme details					
Country	**Year established***	**Funding source**	**Distribution facilities**	**Type of THN***	**Target groups**
Austria	2018	Local level	Distributed through a low threshold facility	Nasal spray (2x 1.8mg/0.1ml per kit)	People who use opioids
Catalonia (Spain)	2008	Funded by regional public health authority	Distributed through low threshold facilities	Ampoules (2x 0.4mg/ml per kit + 2 syringes)	People who use opioids
Denmark	2010	Various sources: municipal treatment funded by government block grants. Private treatment facilities charge municipalities, and NGOs distributing THN are financed by public funds and private charity	Distributed primarily through treatment facilities.	Nasal spray (1-2x 1.8mg/0.1ml per kit)	People who use opioids (in treatment) People who use opioids Relatives, and professionals from other services
England[1]	2001	Local level	Distributed through addiction clinics, GP shared care, homeless hostels, community pharmacies and outreach. Some distribution to people leaving prison, and the police have started to carry nasal spray in limited numbers	Pre-filled syringes (1x 2mg/2ml per kit); ampoules (1x 0.4mg/ml per kit; London only); nasal spray (2x 1.8mg/0.1ml; police only)	People who use opioids (in treatment) People who use opioids Relatives, and professionals from other services Police (Birmingham only)
Estonia	2013	Central government	Distributed through addiction treatment centres (mainly OMT) in collaboration with low threshold facilities.	Pre-filled syringes (1x 2mg/2ml per kit); ampoules (0.4mg/ml); nasal spray (2x 1.8mg/0.1ml; police only)	People who use opioids (in treatment) People who use opioids Relatives, and professionals from other services
Lithuania	2016	Funded by Republican Centre for Additive	Distributed through addiction services, low threshold facilities, outpatient	Ampoules (1x 0.4mg/ml + syringe per kit)	People who use opioids

		Disorders allocations & Drug Tobacco and Alcohol Control Department allocations	centres, and upon leaving inpatient treatment centres		
Northern Ireland	2012	Funded by Public Health Agency Northern Ireland	Distributed through community addiction services, low threshold services, and emergency departments	Pre-filled syringes (1x 2mg/2ml per kit); nasal spray (2x 1.8mg/0.1ml)	People who use opioids
Norway	2014	Funding from central government	Distributed through low threshold facilities, shelters, and street outreach.	Nasal spray (2x 1.26mg/0.1ml per kit or 2x 1.8mg/0.1ml per kit)	People who use opioids Relatives, and professionals from other services Police, security staff
Scotland	2011	Funded mainly by regional health authorities and alcohol & drug partnerships[2]	Distributed mainly via community addiction treatment and low threshold facilities, pharmacies and to at-risk prisoners on release. Peer-to-peer naloxone supplies have also been increasing in recent years. National Click and Deliver Service	Pre-filled syringes (1x 2mg/2ml per kit), nasal spray (2x 1.8mg/0.1ml per kit)	People who use opioids Relatives, peers and professionals from other services, including police. Any member of the public who may witness an overdose
Sweden	2018	Funding from central government	Distributed through low threshold facilities	Nasal spray (1-2x 1.8mg/0.1ml per kit)	People who use opioids
Wales	2011	Funding from central government	Distributed through low threshold facilities, specialist treatment centres, homeless hostels and substance misuse related support housing, prisons, and	Pre-filled syringes (1x 2mg/2ml per kit), nasal spray (2x 1.8mg/0.1ml per kit)	People who use opioids Relatives, and professionals from other services Criminal justice staff

			community-based criminal justice intervention services. Peer-to-peer naloxone supplies have initiated during 2021.		

* Based on EMCDDA (EMCDDA, 2020c, 2021)
[1] From two cities in England (London and Birmingham)
[2] Strategic groups containing key partners which have responsibility for addressing alcohol and drug issues in local communities (e.g., agencies providing health, social care, and criminal justice services)
Opioid maintenance treatment (OMT)

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